UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,166	06/27/2003	Alan J. Mautone	SDR-03DIV	8257

7590 11/30/2005

Richard L. Strauss, Esq.
2492 Oceanside Road
Oceanside, NY 11572

EXAMINER	
GRAFFEO, MICHEL	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,166	MAUTONE, ALAN J.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1-64 are pending and examined.

In the response to the Office Action dated 24 March 2005, Applicant has amended claims 1 and 43 and provided arguments for the patentability of claims 1-64.

In light of Applicant's Amendment dated 24 June 2005, the rejection to claims 1 and 43 under 35 USC §112 has been withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 55-77 of U.S. Patent No.

6,616,913 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a process of preparing a Eustachian tube lumen patency and performance enhancing medicament. The prior art claims are drawn to a method of preparing a Eustachian tube lumen patency medicament. The instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claims 55-77 requires the particular lipid surfactants, spreading agents and propellants. It differs in that the instant claims include sterols, lipids and fatty acids in the group of spreading agents. Since, for example, sterols generally would be included in cholesteryl esters, it would have been obvious to anyone of ordinary skill in the art that the claims overlap in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). The selection of particular lipids, fatty acids and sterols, are all conventional in the lipid surfactant art and would have been obvious with the broad recitation of lipid surfactant.

2. Claims 20-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 78-108 of U.S. Patent No. 6,616,913. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a process for

preparing an otitis media medicament. The prior art claims are drawn to a process for preparing an otitis media medicament. The instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 78-108 requires the particular spreading agents and instant claims 43-64 do not recite spreading agents. However, it is noted that there is overlap in the agents recited as spreading agents that the agents recited as lipid surfactants. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

3. Claims 1-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-86 and 111-133 of U.S. Patent No. 6645467 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because generally the process for preparing the Eustachian tube lumen patency medicament and the process of preparing the otitis media medicament of the instant claims appears to substantially overlap with the process for preparing an upper respiratory airway enhancing medicament. The same components and limitations apply to both processes differing only in the intended use of the process. It would have been obvious to prepare medicaments to enhance

Eustachian tube lumen patency motivated by the process of the prior art wherein an upper airway enhancing medicament is prepared with the same components in the same manner.

4. Claims 1-64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-84 and 108-130 of copending Application No. 2002/0076383 (10/011626). Although the conflicting claims are not identical, they are not patentably distinct from each other because generally the process for preparing the Eustachian tube lumen patency medicament and the process of preparing the otitis media medicament of the instant claims appears to substantially overlap with the process for preparing an external auditory canal patency enhancing and protective medicament of the prior art. The same components and limitations apply to both processes differing only in the intended use of the process. It would have been obvious to prepare medicaments to enhance Eustachian tube lumen patency motivated by the process of the prior art wherein an external auditory canal patency enhancing medicament is prepared with the same components in the same manner.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-102 of U.S. Patent No.

6521213. Although the conflicting claims are not identical, they are not patentably distinct from each other because generally the process for preparing the Eustachian tube lumen patency medicament and the process of preparing the otitis media medicament of the instant claims appears to substantially overlap with the process for preparing an otitis externa medicament of the prior art. The same components and limitations apply to both processes differing only in the intended use of the process. It would have been obvious to prepare medicaments to enhance Eustachian tube lumen patency motivated by the process of the prior art wherein an otitis externa medicament is prepared with the same components in the same manner.

6. Claims 20-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,306,483. Although the conflicting claims are not identical, they are not patentably distinct from each other because generally the process for preparing the Eustachian tube lumen patency medicament and the process of preparing the otitis media medicament of the instant claims appears to substantially overlap with the process for preparing lipid crystals in combination with a therapeutically active agent of the prior art. The same components and limitations apply to both processes differing only in the intended use of the process. It would have been obvious to prepare medicaments to enhance Eustachian tube lumen patency motivated by the process of the prior art wherein lipid crystals in combination with a therapeutically active agent is prepared with the substantially the same components in the same manner.

Response to Arguments

The Terminal Disclaimer filed 24 June 2005 was received, but it makes reference to Application No. 10/011626. Appropriate correction is required.

Applicant's arguments filed 24 June 2005 have been fully considered but they are not persuasive. Applicant's arguments are based on the basic premise that the scope of the instant claims, directed to the process for making a medicament, are not coextensive with the claims of the patents and applications cited in the prior Office Action because the ultimate use for the medicaments are somewhat different.

In response to applicant's arguments, the recitation "for preparing an otitis externa medicament" for example in claim 108 of the '383 Application has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Therefore, if the claimed medicament is capable of performing the functions recited in the referenced patents and applications, then it is coextensive with the claim to which it is compared. In other words, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in

order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

28 November 2005
MG

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600